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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 10/646,682
Filing Date: August 22, 2003
Appellant(s): FERNANDEZ, DENNIS S.

Dennis S. Fernandez
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 07/06/2010 appealing from the Office action mailed 02/03/2010.

**(1) Real Party In Interest**

The examiner notes the real party of interest identified in the appeal brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The following is a list of status of all claims, including those that are rejected and pending in the application:

Claims 1-35 are cancelled.

Claim 50 is withdrawn from further consideration.

Claims 36-49 and 51-55 are rejected and pending in the instant application.

**(4) Status of Amendments After Final**

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

**(5) Summary of Claimed Subject Matter**

The examiner has no comment on the summary of claimed subject matter contained in the brief.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS."

Claims 36-49 and 51-55 are rejected under 35 USC 103(a) as being unpatentable over Porat et al. (US Patent No. 6,432, 050) in view of Giuffre (US Patent No. 6,042,548).

**WITHDRAWN REJECTIONS**

The rejection of claims 36-49 and 51-55 rejected under 35 USC 112, first paragraph, for failing to comply with the written description requirement has been with drawn in view of arguments presented by appellant in the Appeal Brief filed on 07/06/2010.

The rejection of claims 36-49 and 51-55 rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of arguments presented by appellant in the Appeal brief filed on 07/06/2010.

**(7) Claims Appendix**

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

**(8) Evidence Relied Upon**

| | | |
|---|---|---|
| 6,432,050 | Porat et al. | 08-2002 |
| 6,042,548 | Giuffre | 03-2000 |

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 36-49 and 51-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porat et al. (US Patent No. 6,432,050) in view of Giuffre (US Patent No. 6,024,548).

The instant claims are drawn to an integrated biosensor and simulation system and its related method of use. The system comprises at least one implantable biosensor for sensing a biological target to generate a signal, a simulator comprising a systems-biology platform for generating a therapeutic or diagnostic output, wherein said

simulator is reconfigurable by said simulator, such reconfiguration thereby reconfiguring a biocatalyst chip, a logic device, a tissue scaffold, a therapeutic reservoir, or a DNA microarray. The related method of use comprises the steps of sensing a biological target to generate a signal, simulating using said signal and a model of the biological target to generate a therapeutic or diagnostic output.

Porat et al. sets forth systems and methods of use for an improved, implantable biosensor system for monitoring and optionally alleviating a physiological condition in a patient (see Porat et al., Abstract and throughout). The disclosed biosensors of Porat et al. are taught as an improvement to known medical monitoring and measurement devices capable of tolerating internal physiological conditions (see Porat et al. col. 1, lines 35 through col. 2, line 60 and col. 7, line 17 through col. through col. 8, line 29), , which reads on at least one implantable biosensor/sensor as instantly claimed. The disclosed biosensors are also taught as being capable of generating and receiving signals with regard to a specific biological target (see Porat et al., col. 3, lines 35-61, col. 7, lines 17-47, col. 11, lines 3 through 58). Porat et al. further teaches embodiments wherein the an implantable biosensor system comprising a shunt a having fluid passageway and being operable for draining fluid through a fluid passage way from a portion of the patient body (see Porat et al., col. 3, line 62 through col. 4, line 19), which reads on a reconfigurable sensor, wherein reconfiguration involves reconfiguring a therapeutic reservoir as instantly claimed.

While Porat et al., teaches the above described implantable biosensors and their related use in monitoring and optionally alleviating a physiological condition, Porat et al.

does not expressly teach the use of the disclosed biosensors in combination with a simulator system comprising a system-biology platform and a model to generate a therapeutic or diagnostic output.

Giuffre discloses a monitoring means of registering and/or predicting changes in brain and central nervous system activity by using a combination of simulation and biosensor derived signals ( See Giuffre, Abstract, col. 4, lines 6-17, and claims 1, 5, 7, 8, 12, and 18). Giuffre teaches that neurophysiological monitoring equipment increases the demands on the operator, raises costs of care, and if improperly used, leads to mistaken interpretation and, further, discloses a system that allows for predictive capabilities while minimizing risk, cost, and added complexity (see Giuffre col. 1, lines 7-25). Giuffre teaches that the disclosed methodology relies upon generating a trained computer model based on real-time information gathered from biosensor signals (Giuffre, col. 8, line 24 through col. 9, lines 49). Giuffre discloses a programmable computer simulation of brain activity using signal data and a model to estimate brain and central nervous system activity (see Giuffre, col. 4, line 6 through col. 5, line 11), which reads on a simulation comprising a system-biology platform and the process step of simulating using the signal and a model of the target to generate a therapeutic or diagnostic output. Further, in light of the instant specification, a "systems-biology platform" (see page 36, line 16-20) in interpreted as a system that uses software for analyzing computational behavior of a biological system. Giuffre discloses embodiments of trained neural net and self-teaching computer systems that act in real-time to incrementally perturb a system and/or change models until data management is optimal

(see Giuffre, Fig 3., col. 4, lines 6-60 and col. 6, lines 53-59), which reads on a sensor reconfigurable by a simulator, as recited in claims 36 and 40, and the process step of a simulator reconfiguring a sensor, as recited in claim 40.

Giuffre further teaches the detection of drug infusions and drug and alcohol levels in the blood for use in the disclosed method and a system for registering changes in brain and central nervous system activity (see Giuffre, col. 7, line 44 through col. 8, line 2), which reads on a sensor that senses a food material (e.g. alcohol) for consumption by a biological target, the generation of a second signal therefrom, and the use of said second signal to generate a therapeutic or diagnostic output as recited claims 37 and 41. Giuffre teaches generating an output according to a regulatory condition by the disclosed simulation system (see Giuffre, col. 7, line 44 through col. 8, line 24), as recited in claims 38 and 42. Giuffre discloses coupling using a trained neural net and self-teaching computer systems (a switch) (see Giuffre, Figs. 1-3 and col. 4, lines 6-60), which reads on a sensor coupled to a simulator via a programmable switch as recited in claims 39 and 43.

Giuffre further teaches the use of separate biosensors for the heart and brain (see Giuffre, col. 4, lines 6-38), which reads on the implantation of a biosensor for the heart and brain, as recited in claims 44 and 52, an array of at least two sensors capable of sensing two different biological targets, as recited in claims 45, 46, 49, 53, and 54, and a neural biological target, as recited in claims 47 and 55. Giuffre further teaches that the disclosed method relies upon neurophysiological and cardiovascular monitoring from said biosensors for training a neural network (see Giuffre, col. 3, lines 55-61 and

col. 4, lines 6-60). Following the training of a neural network, Giuffre further teaches that only cardiovascular monitoring by heart associated biosensor and the trained neural network are relied upon to estimate the neurophysiological state of a patient (see Giuffre, col. 4, lines 17-38), which reads on the elected species of reconfiguration comprising activating or deactivating at least one biosensor, as recited in claims 48, 49, 51, and 54.

Therefore it would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to use the improved biosensors systems, set forth by Porat et al., with the biosensors for use in the method and a system for registering changes in brain and central nervous system activity by using simulation and signals derived from biosensors, as taught by Giuffre, because Giuffre specifically teaches that the disclosed systems address the complexity of such integrated systems. Giuffre et al. recognizes that the disclosed system allows for new predictive capabilities involving the use of biosensors in a broad range of applications. Giuffre expressly teaches a system and method of use involving monitoring a neurophysiological state by means of a biosensing device. One of skill in the art would be motivated to use the improved biosensor device as taught by Porat et al. as a neurophysiological monitoring device, because Porat et al. teaches said device as an improvement over those known in the prior art and because Giuffre disclosed a system is taught as being adaptable (see Giuffre col. 1, lines 7-25). One of skill in the art would also recognize that the disclosed method of Giuffre requires the use of a neurophysical sensor means (see for example, claims 1 and 12 of Giuffre) and that

Porat et al. teaches a specific embodiment of biosensor for monitoring internal conditions near the brain and spine (see Porat et al., col. 1, lines 35-42). Therefore, based on the expressed teachings of the art, one of ordinary skill in the art would be motivated to seek out and use the improved biosensor device of Porat et al. for use as the neurophysiological monitoring means as required by the systems and method of Giuffre.

**(10) Response to Argument**

In regards to the rejection of claims under 35 USC 103(a) as being unpatentable over Porat et al. (US Patent No. 6,432,050) in view of Giuffre (US Patent No. 6,024,548), appellants first argue that neither Porat nor Giuffre teach an integrated biosensor containing a systems-biology platform (pages 27-29 of appeal brief, filed 07/06/2010).

In response, it is first noted that the instant claims recite that the systems biology platform as comprising "computational modeling hardware and software analysis genomics, proteomics, computational chemistry, pharmacogenomics, computational biology, computational biophysics, computational cell behavior, pharmacokinetics, metabolomics, or transcriptomics automated tools" (see all independent claims). Appellant specifically argues that neither Porat et al. nor Giuffre mention specific hardware or software tools that pertain to genomics, proteomics, computational chemistry, or the seven related fields listed in independent claims 36 and 40. Contrary to appellant's assertion, neurological and cardiovascular monitoring and modeling set

forth by Giuffre (see col. 1, line 27 through col. 4, line 2) encompasses the fields of computational modeling and analysis genomics, proteomics, chemistry, pharmacogenomics, biology, biophysics, cell behavior, pharmacokinetics, metabolomics, or transcriptomics as instantly claimed.

It is maintained that the combination of teachings of Porat et al. in view of Giuffre renders obvious the "integrated biosensor containing a systems biology platform". It is maintained that Porat et al. discloses both systems and methods of use for an implantable biosensor system (see Porat et al., Abstract). The disclosed use of said implantable biosensor requires that it generate a detectable electrical signal coupled, directly or indirectly, to a sensor, wherein the sensor is specifically described in one embodiment as a first acoustic transducer capable of relaying acoustic signals outside a patient's body (see Porat et al., col. 3, lines 35-61). Giuffre discloses methods and related computer systems for registering changes in brain and central nervous system activity and modeling simulations based on real time information derived from biosensors in the context of computer simulation (see Giuffre, Abstract, col. 4, lines 6 through col. 5, line 11, and col. 9, lines 26-37). The combination of the biosensors of Porat et al. as the source of real-time information used in the disclosed system activity monitoring and real-time modeling simulation methodologies as taught by Giuffre is sufficient to meet all recited limitations of the integrated biosensor containing a systems-biology platform as instantly claimed.

Appellant further argues that a person having ordinary skill in the art at the time of this invention would have understood "integrated" to mean constructed on a single piece of material such as a semiconductor wafer.

In response, it is noted that the combination of prior art relied upon in the instant rejection would produce an integrated system within the scope of the invention as instantly claimed. The fundamental combination would contain the biosensors of Porat et al. as the source of real-time information used in the disclosed system activity monitoring and real-time modeling simulation methodologies as taught by Giuffre. It is further noted and emphasized that the only structure recited in the instantly claimed system is at least one implantable biosensor for sensing a biological target and for generating a signal and a simulator. There is no disconnect between the signals generated by the biosensors of Porat et al., that measure/monitor a particular biological target, to the computational systems taught by Giuffre that monitor brain and central nervous system activity as well as perform the modeling simulations based on real time information derived from biosensors.

Appellant further argues that the acoustic biosensor of Porat and the method and system of cardiovascular monitoring of Giuffre cannot be effectively combined. Specifically, appellant contends that combining the implantable piezoelectric sensor of Porat and the cardiovascular monitoring method of Giuffre will render the piezoelectric sensor unsatisfactory for its intended purpose.

In response to appellant's argument, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). It is noted that the "at least one biosensor" as recited in the instant claims is not limited to being a device specific to cardiovascular monitoring. Similarly, the disclosed biosensors of Porat et al. are not limited to being devices specific only to cardiovascular monitoring. To the contrary, Porat et al. teaches that the disclosed biosensing systems encompass a broad range of physiological conditions (see Porat et al., col. 1, line 35 through col. 2, line 60). One particular embodiment set forth by Porat et al. specifies that monitoring internal conditions near the brain and spine are of particular importance (see Porat et al., col. 1, lines 35-42). The disclosed method and system of cardiovascular monitoring of Giuffre also requires a brain monitoring means (see for example Giuffre, claims 1 and 12). Appellant's argument only contends that one of skill in this art would not attempt to substitute a biosensor, as taught by Porat et al., with the cardiovascular monitoring means by Giuffre (see also Giuffre, claims 1 and 12). Appellant's argument however does not provide any negative teaching that bar the use of all the other biosensor embodiments of Porat et al. Since Porat et al. specifies that monitoring internal conditions near the brain and spine are of particular importance (see Porat et al., col. 1, lines 35-42), one of skill in the art would be motivated to seek out and use an improved biosensor, as taught by Porat et al., for the brain monitoring means as taught by Giuffre.

Appellant further argues that there no reasonable expectation of success where prior art discourages use of piezoelectric biosensors for genomic applications. Appellant specifically asserts that the piezoelectric biosensor as taught by Porat et al. is incompatible as the cardiovascular monitoring device used in the methodology set forth by Giuffre.

In response, it is reiterated that neither the instant claims nor the biosensors of Porat et al. are limited to cardiovascular monitoring devices. Appellant's argument only demonstrates that one of skill in this art would know not to use an interfering piezoelectric device, whose bioimpedence causes pacemaker malfunction, as a cardiovascular monitoring device. This argument does not support the dismissal of all biosensor embodiments disclosed and taught by Porat et al. As argued above, the disclosed systems and method of Giuffre require a brain monitoring means (see for example Giuffre, claims 1 and 12). It is maintained that the improved biosensor of Porat et al., directed to the monitoring internal conditions in the brain (see Porat et al., col. 1, lines 35-42) are suitable for use in the system and method taught by Giuffre.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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